

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

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| <b>TITLE (PROVISIONAL)</b> | Effectiveness of a guided online mindfulness-focused intervention in a student population: Study protocol for a randomized control trial                      |
| <b>AUTHORS</b>             | Schultchen, Dana; K  chler, Ann-Marie; Schillings, Christine; Weineck, Felicitas; Karabatsiak  s, Alexander; Ebert, David; Baumeister, Harald; Pollatos, Olga |

### VERSION 1 – REVIEW

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| <b>REVIEWER</b>        | Marlon Danilewitz<br>University of British Columbia |
| <b>REVIEW RETURNED</b> | 03-Sep-2019   |

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| <b>GENERAL COMMENTS</b> | Comprehensive |
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| <b>REVIEWER</b>        | Dr. Michelle O'Driscoll<br>University College Cork<br>Ireland |
| <b>REVIEW RETURNED</b> | 11-Oct-2019   |

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| <b>GENERAL COMMENTS</b> | <p>This is a very comprehensive, interesting and topical study protocol, which takes into excellent consideration the need for a scientifically robust approach to the design of mindfulness-based intervention studies.</p> <p>In general the language used is good. However, there are minor grammatical/phrasing issues throughout the manuscript which should be addressed prior to publication.</p> <p>Excellent point that objective measurement of the effects of mindfulness rather than self reporting has not yet been carried out for online interventions.</p> <p>A suggestion about course design - Week 7 would seem to fit better earlier on in the course. Mindfulness Based Stress Reduction, the gold standard of MBIs uses mindful eating as one of the very first activities for participants to try. The whole basis of mindfulness is coming into the present moment by using the senses and the body as an anchor. Week 7 seems very late to be introducing these activities..</p> <p>The booster sessions speak about repeating modules. Would it be more accurate to say that they summarise or review modules?</p> |
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|  | <p>It is stated that the significance level for all analyses will be <math>p \leq .05</math>. How do you propose to allow for multiplicity of testing, considering the extensive number of measurements being taken?</p> <p>Abstract background - clarify what you mean by "offer flexibility", I assume it's flexibility for participants?</p> <p>Use of e.g. with citation numbers not appropriate. It is enough to list the citations.</p> <p>Explain what is meant by "therapeutic guidance" (pg6 line 8)</p> <p>A very interesting study, I look forward to hearing about your findings!</p> |
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| <b>REVIEWER</b>        | <p>Florian Hammerle<br/>Department of Child and Adolescent Psychiatry, University Medical Centre, University Mainz, Germany</p> |
| <b>REVIEW RETURNED</b> | 19-Dec-2019   |

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| <b>GENERAL COMMENTS</b> | <p>Thank you for the opportunity to review the editorial manuscript 'The effectiveness of a guided online mindfulness-based intervention for the prevention of stress in a student population: Study protocol for a randomized control trial', describing a study protocol for a guided online mindfulness-based intervention.</p> <p>The topic is of high relevance. Although the main aim of the study and the randomized approach with follow up is very promising – and I really think the study and the approach are very interesting- I have some major concerns.</p> <p>The manuscript includes some conclusions (mainly in the background) which are too strong, it is in some parts unstructured (missing aspects of the methods as aims and measurements in the background) and includes a combination of different preventive/treatment approaches (ACT, stress management, mindfulness) and a very large set of different primary, secondary and co-variate variables. I would strongly recommend to review the background and the drawn conclusions, to focus the manuscript and to match all parts of the manuscript.</p> <p>Please find my specific recommendations below.</p> <p>One main problem is that the intervention is called solely "mindfulness". In the methods, page 11, 11-13 the treatment is based in ACT and stress management. Although ACT includes some aspects of mindfulness, it also incorporates aspects of strong commitment to one's life goals and stress management is regularly based on behavioral interventions as second-wave interventions in CBT (e.g. time management and challenging one's dysfunctional beliefs). When considering table 1. core CBT-strategies (e.g. developing beneficial thoughts) are mentioned, which can be used besides or additional to mindfulness techniques but are completely separate techniques than mindfulness. The same seems true for module 5. "what makes you valuable" which is a standard ACT-technique and some steps away from core mindfulness. At least the program seems to be a combination of mindfulness and CBT- and ACT-techniques, which should be mentioned in the title, background and methods.</p> |
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|  | <p><b>Title</b><br/>The title is misleading. First, interventions are based on ACT and classic stress reduction techniques (e.g. Kaluza), associated with second wave CBT-techniques of challenging dysfunctional thoughts and beliefs together with mindfulness interventions. Secondly, primary aims are increases in mindfulness and secondary aims include (in this order) expected reductions in anxiety depression, stress levels, well being and psychobiological markers (and a large set of several other aims and covariates). The aspect of the “prevention” of stress is therefore misleading.</p> <p><b>Abstract</b><br/>Beside the other recommendations of focusing the manuscript, the abstract seems good.</p> <p><b>Strengths/Limitations</b><br/>The aim to increase mindfulness, decrease stress and reduce mental disorders seems very straightforward and especially mental disorders are only assessed with validated, but very short self-report measures. This strength should be reformulated and attenuated.</p> <p>Additionally, a six month follow-up leads to analyzing some longitudinal effects, but “long-term effects” with a six month follow-up seems a to strong wording.</p> <p><b>Background</b><br/>At the first read the background addresses the relevant issues. Checking the references (e.g. Auerbach et al., 2016) revealed incomplete conclusions. The major conclusion in the section lines 16-21 is that studying seems associated with higher prevalences of mental disorders. Auerbach et al. state that 20% of students had a 12-month DSM-IV disorder, BUT 83.1% of the cases had a pre-matriculation onset and have therefore begun before studying. I strongly recommend to check the background carefully and not to draw too strong conclusions although the prevention and treatment of mental disorders in students (independent of the onset) seems an absolutely relevant topic.</p> <p>Also, line 42-45 seem not correctly deduced from the references. References 32-34 show that internet-based programs are effective. There are no comparisons to face-to-face interventions. Although the argument in favor of internet programs (low threshold etc.) seems correct , I would recommend a more accurate literature review. E.g. Andersson, et al. (2016) “Guided Internet-based vs. face-to-face cognitive behavior therapy for psychiatric and somatic disorders: a systematic review and meta-analysis“ compared internet based interventions and face-to-face-programs and showed comparable effects for anxiety disorders, depressive symptoms and psycho-somatic disorders.</p> <p>I really think internet-based prevention and intervention could be effective and are promising approaches, but the literature-processing in the manuscript is inaccurate and should be revised.</p> <p>Mindfulness (page 6, lines 10-14): although mindfulness is an accepting and non-jugmental way, it can not only directed inwards (breathing/bodily sensations as in some mediation practices) but also at the “world” around as acknowledging sounds, pictures or movement and behavior (e.g. Dimidjian, Sona, and Marsha M. Linehan. "44 MINDFULNESS PRACTICE." General principles and empirically supported techniques of cognitive behavior therapy (2009): 425). This section should be revised.</p> |
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|  | <p>At the end of the background, the conclusion that psychobiological data are more reliable (and therefore better) is too strong. Psychobiological data complements self-report and/or interview information and vice versa. I really appreciate the inclusion of psychobiological data and think this is one strength of the study. But- psychobiological variables could also be less valid in terms of criterion validity. In summary, the conclusions in the background either drawn from literature or from methods are too strong and should be revised/attenuated.</p> <p>The secondary outcome “gene FKBP5” is not mentioned in the background and should be included. In the manuscript no theoretical framework is mentioned in the background.</p> <p>I don’t understand hypothesis 3. “The relationship between secondary outcome and different covariates are also significant”. Besides the language, covariates have not been mentioned in the background. Therefore no theoretical framework is presented, and possible covariations seem unclear. I think the hypothesis’ section should be revised and focused on the main issues.</p> <p><b>Methods</b><br/> The language page 9, lines 3-5 “The project takes part in collaboration with the Department for Clinical Psychology and Psychotherapy of Ulm University.” seems awkward and I don’t understand the nature of a collaboration with one department. Maybe the collaboration takes place between the University of Ulm and Amsterdam?</p> <p>Under Assessments and Outcome, page 12, lines 58/59 a heartbeat perception task is mentioned, which has not been mentioned before. Please include the measurement in the background/hypothesis.</p> <p>Figure 1: I would recommend a higher resolution.</p> <p>Although I am not a native speaker, the language seems in some parts not fully correct (e.g. Background, line 5/6 “showed significantly higher stress levels...”). I think the correct wording would be “significant higher stress levels”. Another example: page 6, lines 58, 59, 60: therefore, “accomplish self report data”. I think the authors mean to say “to complement/augment” or else. Another example: page 10, line 17-19: “Depending on which University participants are from, they are either allocated to ...” In turn, I would recommend a language check.</p> |
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## VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name

Marlon Danilewitz

Institution and Country

University of British Columbia

Please state any competing interests or state 'None declared': None Declared

Please leave your comments for the authors below Comprehensive

Response: We appreciate this suggestion and differentiate between competing interests and author contributions (see p. 20, l. 14-16).

Reviewer: 2

Reviewer Name

Dr. Michelle O'Driscoll

Institution and Country

University College Cork Ireland

Please state any competing interests or state 'None declared':  
None declared

Response: Thank you for this suggestion. We edited this accordingly (see p. 20, l. 14/15).

Please leave your comments for the authors below This is a very comprehensive, interesting and topical study protocol, which takes into excellent consideration the need for a scientifically robust approach to the design of mindfulness-based intervention studies.

In general the language used is good. However, there are minor grammatical/phrasing issues throughout the manuscript which should be addressed prior to publication.

Response: Our manuscript was checked again by a native speaker.

Excellent point that objective measurement of the effects of mindfulness rather than self reporting has not yet been carried out for online interventions.

Response: Thank you very much for this point!

A suggestion about course design - Week 7 would seem to fit better earlier on in the course. Mindfulness Based Stress Reduction, the gold standard of MBIs uses mindful eating as one of the very first activities for participants to try. The whole basis of mindfulness is coming into the present moment by using the senses and the body as an anchor. Week 7 seems very late to be introducing these activities..

Response: Thank you very much for this advice, which is very helpful. We will include this in a future manuscript – especially in the discussion part. At the moment, we assessed 60% of our sample. Consequently, it is not very useful to change this at this time.

The booster sessions speak about repeating modules. Would it be more accurate to say that they summarise or review modules?

Response: We have specified this on p. 10, l. 1-3.

It is stated that the significance level for all analyses will be  $p \leq .05$ . How do you propose to allow for multiplicity of testing, considering the extensive number of measurements being taken?

Response: Thank you, and we agree with you. Consequently, we have included this more specific: "...will be adjusted for multiple comparisons using the Holm-Bonferroni correction method" (p. 17, l. 23).

Abstract background - clarify what you mean by "offer flexibility", I assume it's flexibility for participants?

Response: We modified this part (see p. 2, l. 4-6)

Use of e.g. with citation numbers not appropriate. It is enough to list the citations.

Response: We deleted all "e.g." in the whole manuscript in combination with citations.

Explain what is meant by "therapeutic guidance" (pg6 line 8)

Response: We mean that participants get support from an expert online or face-to-face. Consequently, it is not a stand-alone approach. We added this part (see p. 5, l. 4-6).

A very interesting study, I look forward to hearing about your findings!

Reviewer: 3

Reviewer Name

Florian Hammerle

Institution and Country

Department of Child and Adolescent Psychiatry, University Medical Centre, University Mainz, Germany

Please state any competing interests or state 'None declared':  
None declared

Response: Thank you for this suggestion. We edited this accordingly (see p. 20, l. 14/15).

Please leave your comments for the authors below Thank you for the opportunity to review the editorial manuscript 'The effectiveness of a guided online mindfulness-based intervention for the prevention of stress in a student population: Study protocol for a randomized control trial', describing a study protocol for a guided online mindfulness-based intervention.

The topic is of high relevance. Although the main aim of the study and the randomized approach with follow up is very promising – and I really think the study and the approach are very interesting- I have some major concerns.

The manuscript includes some conclusions (mainly in the background) which are too strong, it is in some parts unstructured (missing aspects of the methods as aims and measurements in the background) and includes a combination of different preventive/treatment approaches (ACT, stress management, mindfulness) and a very large set of different primary, secondary and co-variate variables. I would strongly recommend to review the background and the drawn conclusions, to focus the manuscript and to match all parts of the manuscript.

Please find my specific recommendations below.

One main problem is that the intervention is called solely “mindfulness”. In the methods, page 11, 11-13 the treatment is based in ACT and stress management. Although ACT includes some aspects of mindfulness, it also incorporates aspects of strong commitment to one’s life goals and stress management is regularly based on behavioral interventions as second-wave interventions in CBT (e.g. time management and challenging one’s dysfunctional beliefs). When considering table 1. core CBT strategies (e.g. developing beneficial thoughts) are mentioned, which can be used besides or additional to mindfulness techniques but are completely separate techniques than mindfulness. The same seems true for module 5. “what makes you valuable” which is a standard ACT-technique and some steps away from core mindfulness. At least the program seems to be a combination of mindfulness and CBT- and ACT-techniques, which should be mentioned in the title, background and methods.

Response: Thanks for this comment. We agree that the intervention does not only include mindfulness techniques. However, the main focus of the intervention is mindfulness. Hence, we changed the title to "mindfulness-focused" instead of "mindfulness-based" and described the intervention more clearly as a mindfulness-focused intervention including also CBT and ACT techniques (see p. 10, l. 12-16).

#### Title

The title is misleading. First, interventions are based on ACT and classic stress reduction techniques (e.g. Kaluza), associated with second wave CBT-techniques of challenging dysfunctional thoughts and beliefs together with mindfulness interventions. Secondly, primary aims are increases in mindfulness and secondary aims include (in this order) expected reductions in anxiety depression, stress levels, well being and psychobiological markers (and a large set of several other aims and covariates). The aspect of the “prevention” of stress is therefore misleading.

Response: Thanks for this comment. We deleted the stress prevention focus in the title. The title now reads "Effectiveness of a guided online mindfulness-focused intervention in a student population: Study protocol for a randomized control trial".

#### Abstract

Beside the other recommendations of focusing the manuscript, the abstract seems good.

#### Strengths/Limitations

The aim to increase mindfulness, decrease stress and reduce mental disorders seems very straightforward and especially mental disorders are only assessed with validated, but very short selfreport measures. This strength should be reformulated and attenuated.

Response: We tried to tone down our language and reformulate this bullet point with a higher focus on our aim to increase mindfulness, decrease stress level and reduce mental disorders. (see p. 2, l. 33/34).

Additionally, a six-month follow-up leads to analyzing some longitudinal effects, but “long-term effects” with a six-month follow-up seems a to strong wording.

Response: We deleted long-term effects and only wrote that a six months follow-up measurement will be included.

## Background

At the first read the background addresses the relevant issues. Checking the references (e.g. Auerbach et al., 2016) revealed incomplete conclusions. The major conclusion in the section lines 1621 is that studying seems associated with higher prevalences of mental disorders. Auerbach et al. state that 20% of students had a 12-month DSM-IV disorder, BUT 83.1% of the cases had a prematriculation onset and have therefore begun before studying. I strongly recommend to check the background carefully and not to draw too strong conclusions although the prevention and treatment of mental disorders in students (independent of the onset) seems an absolutely relevant topic. Also, line 42-45 seem not correctly deduced from the references. References 32-34 show that internet-based programs are effective. There are no comparisons to face-to-face interventions. Although the argument in favor of internet programs (low threshold etc.) seems correct, I would recommend a more accurate literature review. E.g. Andersson, et al. (2016) “Guided Internet-based vs. face-to-face cognitive behavior therapy for psychiatric and somatic disorders: a systematic review and meta-analysis” compared internet based interventions and face-to-face-programs and showed comparable effects for anxiety disorders, depressive symptoms and psycho-somatic disorders. I really think internet-based prevention and intervention could be effective and are promising approaches, but the literature- processing in the manuscript is inaccurate and should be revised. Mindfulness (page 6, lines 10-14): although mindfulness is an accepting and non-judgmental way, it can not only directed inwards (breathing/bodily sensations as in some mediation practices) but also at the “world” around as acknowledging sounds, pictures or movement and behavior (e.g. Dimidjian, Sona, and Marsha M. Linehan. "44 MINDFULNESS PRACTICE." General principles and empirically supported techniques of cognitive behavior therapy (2009): 425). This section should be revised. At the end of the background, the conclusion that psychobiological data are more reliable (and therefore better) is too strong. Psychobiological data complements self-report and/or interview information and vice versa. I really appreciate the inclusion of psychobiological data and think this is one strength of the study. But psychobiological variables could also be less valid in terms of criterion validity. In summary, the conclusions in the background either drawn from literature or from methods are too strong and should be revised/attenuated.

Response: Thank you very much for your bits of advice. We appreciated this and included these in the manuscript.

- Advice for Auerbach et al. see p. 4 l. 6/7 sowie 9-11.
- Advice regarding the comparison of internet-based and face-to-face intervention see p. 4, l. 27/28; we included your suggested reference as well as some other reference with the focus on ACT and clinical populations.
- Advice and inclusion for the mindfulness part see p. 5, l. 9/10.
- We also tone down our conclusion regarding the psychobiological marker see p. 6 l. 1/2.

The secondary outcome “gene FKBP5” is not mentioned in the background and should be included. In the manuscript no theoretical framework is mentioned in the background.



Response: Thank for your advice. We included the gene more in the theoretical background (p. 6 (l. 35-37)/7 (l. 1-9), instead of using description in the hypothesis part. Further, we also mention that the gene can only assess once and consequently, will be used as a mediator.

I don't understand hypothesis 3. "The relationship between secondary outcome and different covariates are also significant". Besides the language, covariates have not been mentioned in the background. Therefore no theoretical framework is presented, and possible covariations seem unclear. I think the hypothesis' section should be revised and focused on the main issues.

Response: Thank you very much for this advice. We shortened this part and tried to emphasize the main issues. However, covariate analyses are in the method part (see p. 15, starting at l. 27) as well as integrated into the theoretical background (see p. 6, l. 7-9). In our opinion, the theoretical background would be too specific to explain every co-variate. We hope that we aimed your concern.

#### Methods

The language page 9, lines 3-5 "The project takes part in collaboration with the Department for Clinical Psychology and Psychotherapy of Ulm University." seems awkward and I don't understand the nature of a collaboration with one department. Maybe the collaboration takes place between the University of Ulm and Amsterdam?

Response: Thank you for this suggestion. However, we are two different Departments: (1) Clinical and Health Psychology (Ulm University) and (2) Clinical Psychology and Psychotherapy (Ulm University), indicating a cooperation for these two departments.

Under Assessments and Outcome, page 12, lines 58/59 a heartbeat perception task is mentioned, which has not been mentioned before. Please include the measurement in the background/hypothesis.

Response: We included the heartbeat perception task in the background/hypothesis. It is the primary measurement of interoceptive accuracy (see p. 6, l. 6/7 and p. 7, l. 21). However, we only mentioned this shortly and thought that the specific description of this assessment is perfectly placed in the method section. We hope to concern your issue!

Figure 1: I would recommend a higher resolution.

Response: We formatted Figure 1.

Although I am not a native speaker, the language seems in some parts not fully correct (e.g. Background, line 5/6 "showed significantly higher stress levels..."). I think the correct wording would be "significant higher stress levels". Another example: page 6, lines 58, 59, 60: therefore, "accomplish self report data". I think the authors mean to say "to complement/augment" or else. Another example: page 10, line 17-19: "Depending on which University participants are from, they are either allocated to ..." In turn, I would recommend a language check.

Response:

We have edited these parts of the manuscript. Here as well, the manuscript has been checked by a native speaker.

## VERSION 2 – REVIEW

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| <b>REVIEWER</b>        | Florian Hammerle<br>Department of Child and Adolescent Psychiatry, University<br>Medical Centre, University Mainz, Germany |
| <b>REVIEW RETURNED</b> | 04-Feb-2020  |

|                         |  |
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| <b>GENERAL COMMENTS</b> | <p>Thank you for the opportunity to review the augmented version of "Effectiveness of a guided mindfulness-focused intervention in a student population: Study protocol for a randomized control trial". First of all, I very much appreciate the thorough processing of the reviewers' concerns and the authors have been very responsive to the editors and reviewers' concerns. I very much appreciate the modifications and I think the manuscript improved significantly and the conclusions in the background are well balanced.</p> <p>All my concerns have been sufficiently addressed and I look forward to the publication and your results. Best of luck for your research.</p> |
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## VERSION 2 – AUTHOR RESPONSE

Reviewer: 3

Reviewer Name

Florian Hammerle

Institution and Country

Department of Child and Adolescent Psychiatry, University Medical Centre, University Mainz, Germany

Please state any competing interests or state 'None declared':

None declared

Response: We changed this in the last version.

Please leave your comments for the authors below

Thank you for the opportunity to review the augmented version of "Effectiveness of a guided mindfulness-focused intervention in a student population: Study protocol for a randomized control trial".

First of all, I very much appreciate the thorough processing of the reviewers' concerns and the authors have been very responsive to the editors and reviewers' concerns. I very much appreciate the modifications and I think the manuscript improved significantly and the conclusions in the background are well balanced.

All my concerns have been sufficiently addressed and I look forward to the publication and your results. Best of luck for your research.

Response: Thank you for your kind words!